3510-16-P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Deposit of Biological Materials

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. § 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by any of the following methods:

- E-mail: InformationCollection@uspto.gov. Include "0651-0022 comment" in the subject line of the message.
- Mail: Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.
- Federal Rulemaking Portal: http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Raul Tamayo, Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450; by telephone at 571-272-7728; or by e-mail to Raul.Tamayo@uspto.gov with "Paperwork" in the subject line. Additional information about this collection is also available at http://www.reginfo.gov under "Information Collection Review."

SUPPLEMENTARY INFORMATION

I. Abstract

The deposit of biological materials as part of a patent application is required by 35 U.S.C. 2(b)(2) and outlined in 37 CFR 1.801-1.809. Every patent must contain a description of the invention sufficient to enable a person

(knowledgeable in the relevant science), to make and use the invention as specified by 35 U.S.C. 112. The term "biological material" is defined by 37 CFR 1.801 as including material that is capable of self-replication, either directly or indirectly. When the invention involves a biological material, sometimes words and figures are not sufficient to satisfy the statutory requirement for patentability under 35 U.S.C. 112. In such cases, the required biological material must either be: (1) known and readily available (neither condition alone is sufficient) or, (2) deposited in a suitable depository that has been recognized as an International Depositary Authority (IDA) established under the Budapest Treaty, or a depository recognized by the USPTO to meet the requirements of 35 U.S.C. 112.

In cases where a deposit is necessary, it must be made under conditions that assure access to those entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122 and upon issuance as a patent that all restriction to public access is permanently removed.

In order to meet and satisfy requirements for international patenting, all countries signing the Budapest Treaty must recognize the deposit of biological material with any International Depositary Authority (IDA).

II. Method of Collection

By mail, hand delivery, or electronically to the USPTO.

III. Data

OMB Number: 0651-0022.

Form Number(s): None.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 2,001 responses per year. The USPTO estimates that approximately 5% of these responses will be from small entities.

Estimated Time Per Response: The USPTO estimates that it will take the public 1 hour to gather the necessary information, prepare the appropriate form or documents, and submit the information to the USPTO for a deposit of biological materials. The USPTO estimates that it will take the average depository seeking approval to store biological materials approximately 5 hours to collect and submit the necessary approval information.

Estimated Total Annual Respondent Burden Hours: 2,005 hours.

Estimated Total Annual Respondent Cost Burden: $61,855 per year to submit the information to the USPTO. Using the professional hourly rate of $30 for a senior administrative assistant, the USPTO estimates $60,000 per year for salary costs associated with collecting and submitting the necessary deposit information to the USPTO. The USPTO expects that the information in this collection associated with the average depository seeking approval to store biological material will be prepared by attorneys at an estimated rate of $371 per hour, for a total of $1,855. Therefore, the USPTO estimates that the respondent cost burden for this collection will be approximately $61,855 per year.

Item	Estimated time for response	Estimated annual responses	Estimated annual burden hours
Deposited Materials	1 hour	2,000	2,000
Depository Approval	5 hours	1	5
Totals	.....	**2,001**	**2,005**

Estimated Total Annual Non-hour Respondent Cost Burden: $5,938,646. There are no maintenance costs, recordkeeping costs, or filing fees associated with this information collection. However, this collection has annual (non-hour) costs in the form of capital start-up and postage costs.

Depositories charge fees to depositors; all depositories charge about the same rates for their services. For example, the American Type Culture Collection (ATCC), one of the world's leading biological supply houses and recognized patent depositories, offers comprehensive patent services for $2,500 per deposit. Most deposits received from outside the United States require an import permit from the U.S. Department of Agriculture (USDA) as well as a Public Health Service (PHS) permit, available from the Centers for Disease Control and Prevention (CDC), for importation of agents infectious to humans. There is no extra charge for this permit application processing. The USPTO estimates that the total non-hour respondent cost burden in the form of capital start-up costs amounts to $5,000,000.

In addition, this collection does have postage costs. Biological deposits are generally shipped to the depository "Domestic Overnight" by Federal Express (FedEx) and, since depositors are urged to supply frozen or freeze-dried material, it must be packed in dry ice according to a representative from the Patent Department at ATCC. Dry ice itself is considered dangerous goods and requires special packaging. Additional FedEx special handling charges for inaccessible dangerous goods shipments of $37.50 per

shipment apply for temperature-sensitive biological materials and also for the dry ice. An average cost for shipping by FedEx "Domestic Overnight" is estimated to be $75. If the shipment requires pick-up by FedEx, there is an additional charge of $4. Special packaging is also required for these shipments. According to DG Supplies Inc., a supplier of infectious and diagnostic goods packaging, the average cost of frozen infectious shippers is estimated to be $352.82 per package of four for specimen shipments requiring refrigeration or dry ice. Therefore, postage costs average $469.32 per shipment, for a total cost to respondents of $938,640.

The postage cost for a depository seeking recognition is estimated to be $5.95, sent to the USPTO by priority mail through the United States Postal Service. Since the USPTO estimates that it receives one request for recognition from a depository every four years, the average postage cost to respondents is approximately $6 per year.

The USPTO estimates that the (non-hour) respondent cost burden in the form of mailing costs amounts to $938,646.

Therefore, the USPTO estimates that the total (non-hour) respondent cost burden for this collection in the form of capital start-up costs and postage costs is $5,938,646.

IV. Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

The USPTO is soliciting public comments to: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Dated: March 12, 2013

Susan K. Fawcett,

Records Officer, USPTO,

Office of the Chief Information Officer.

BILLING CODE: 3510-16-P

[FR Doc. 2013-06046 Filed 03/14/2013 at 8:45 am; Publication Date: 03/15/2013]